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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,393	10/26/2001	Joel S. Hochman	Athena1	9804

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EXAMINER	
MARMOR II, CHARLES ALAN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,393	HOCHMAN ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Response to Office Action Dated December 16, 2004. The Examiner acknowledges Applicant's Remarks and that no amendments to the Application were made therein. Claims 1-16 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "non-implanted" recited in line 4 of claims 1 and 16 renders the claims indefinite. No special definition of the term is set forth in the specification of the instant application. Therefore, one cannot be certain of the metes and bounds of this term, which is a negative limitation, and thus the scope of the aforementioned claims.

In the Tenth Edition of Merriam Webster's Collegiate Dictionary (1996), the verb "implant" is defined as "to insert in a living site." In view of this "dictionary" definition of the word "implant," the limitation "non-implanted," or essentially not inserted in a living site, used in the claims of the present invention would appear to contradict subsequent limitations of the claims that require the device to be inserted into and contained within the vagina in order to monitor vaginal conditions, and therefore render the claimed apparatus inoperable.

4. The indicated allowability of claims 8-10, 14 and 15 is withdrawn in view of the newly discovered reference to Blythe ('118). Rejections based on the newly cited reference follow.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-7 and 11-16 rejected under 35 U.S.C. 102(b) as being anticipated by Blythe ('118). Blythe teach a vaginal probe for monitoring various conditions within the vagina of a human or animal. The probe includes at least a single, separate unit (10) in the form of a portable, non-implanted, and intravaginally containable combination probe and power source (68). The probe communicates with a separate unit in the form of a computer (75) that sends control signals to the probe to alter the transducing sensors (e.g. turning selected sensors off and on) and receives output signals from the probe (see column 7, lines 16-19) via a connection at interface port (72) and communicates with external networks, devices or databases. In a wireless embodiment, the probe is a single separate unit in the form of a combination probe (10), transponder/transceiver (92), and power source (68). The wireless combination probe (10) may be provided without the

interface port (see column 8, lines 31-34) and the computer will be replaced by a single, separate controller unit (96) that includes a transponder/transceiver (94) and is capable of being handheld for forming a wireless signal feedback loop with the probe unit. The probe unit is adapted to transduce vaginal conditions using a plurality of sensor transducers (42,44,46,48,50,52,56,58) mounted on the probe. The sensors may be used to sense body temperature, the pH of cervical fluids, Luteinising Hormone levels in vaginal fluids, cervical mucus density, estrogen levels, progesterone levels, estradiol levels, and vaginal cavity pressures which are inherently representative of muscle contractions (see column 2, lines 23-29 and 41-44). Other types of sensors may be used (see column 2, line 44). In another embodiment the probe may be adapted to apply treatment material for a condition (medication) such as semen or fertilized eggs to patients suffering from fertility issues (see column 9, lines 7-13). The probe is a sealed unit that may be inserted "in-situ" into the vaginal vault or removed therefrom. Nothing in the disclosure of the Blythe patent suggests that the probe is either expandable or compressible. In operation, the probe unit may be self-inserted by a human subject into the human vagina (see column 7, lines 9-11) and a two-way wireless signal feedback loop may be provided between the combination probe, transponder/transceiver, and power source and the combination controller and transponder/transceiver.

7. Claims 1-7 and 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Guice et al. ('39O). Guice et al. teach a system and method for monitoring the health and status of livestock and other animals. The system includes at least a single, separate unit (50,51,280) in the form of a portable, intravaginally containable combination probe,

transceiver and power source in a single, separate unit (70,72) in the form of a combination controller and transceiver. The use of the transitional term "comprising" in the claim language is inclusive or open-ended and does not exclude additional, unrecited elements (i.e., in addition to the claimed two "single, separate units"). See MPEP 2111.03. The single, separate unit (50,51,280) in the form of a portable, intravaginally containable combination probe, transceiver (see at least paragraph [0124]) and power source (288) is "non-implanted" in a substantially equivalent sense as the limitation is defined in the specification of the instant application (i.e., "intravaginally containable... in situ yet removable" as recited in paragraph [0010]), although the patentee has chosen to call his telesensor an "implant." The Guice implant embodiments of Figs. 18 and 19 (see paragraph [0179]) are in the form of spring-like curved members that can be compressed to a smaller diameter to be inserted into a vaginal cavity, then expand to a larger diameter after being inserted into the vaginal cavity, and are provided with tabs (299) or a wire member (301) to aid in removal of the telesensor implant without the need for incisions or surgery. The probes of Guice et al. (Figures 17-19) are not disclosed as being expandable or compressible along the width of the outer surface of the housing. The combination probe, transceiver and power source of Guice et al. is provided with means for sensing vaginal conditions (292) and 2-way wireless communication means for transmitting information that is transduced and for receiving control and programming signals (see at least paragraph [0124]). The separate combination controller and transceiver is provided with wireless means for sending signals to the probe and for receiving signals therefrom (see at least paragraph [0209]).

A wireless signal feedback loop is provided between the controller and the probe and which may be an interactive or closed signal feedback wireless loop. The probe is a sealed unit which is inserted "in-situ" into the vaginal vault or removed therefrom (see at least paragraph [0135]). The means for sensing vaginal conditions of the probe include sensor transducers (292) that may be provided with means for transducing in the form of a muscle activity sensor (see at least paragraph [0080]); means for sampling temperature changes (see at least paragraph [0106]) in the vaginal environment. The wireless combination controller and transceiver includes means for wirelessly altering operation settings of the probe and means for wirelessly altering the transducing sensor (see at least paragraph [0104]). A wireless means (72) is provided to transmit signals to and/or receive signals from external devices, networks, or databases. The controller may be inclusive of a hand-held unit (e.g., a PDA). The probes (Figs. 17-19) of Guice et al. are capable of being self-applied by a human subject into the human vagina such that vaginal conditions are transduced by the probe.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blythe ('118) in view of Eini et al. ('037). Blythe, as discussed hereinabove, teach a combination probe, transceiver and power source that uses any of a variety of sensors to

monitor conditions within the vaginal cavity including vaginal cavity pressures. Blythe teaches all of the limitations of the claims except that the probe includes stimulating means. Eini et al. teach an intravaginal probe for sensing electrical activity of muscles surrounding the intravaginal cavity via sensors (24) and for electrically stimulating the intravaginal cavity in response to the sensed activity. The stimulation means (14) includes means for automatic adjustment of the stimulation levels in response to changes in the vaginal environment where the adjusting means is either programmed into the stimulating means or remotely adjustable via a wireless signal. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide an intravaginal probe similar to that of Blythe with electrical activity sensors and stimulating means similar to those of Eini et al. in order to sense muscle activity in the vaginal cavity that effects a sensed vaginal cavity pressure and to stimulate vaginal muscles in response to the sensed body conditions of the human subject so as to prevent and treat conditions such as urinary incontinence.

Response to Arguments

10. Applicant's arguments filed March 28, 2005 with regard to the claim rejections under 35 USC § 112 have been fully considered but they are not persuasive. Applicant contends that "non-implanted" is precisely an appropriate and proper term pursuant to FDA guidelines and requirements. Applicant further contends that the term "non-implanted" is the term of the art in the pertinent field, and is therefore definite, requires no definition since it is the term prescribed by the FDA, and is thus recognized by those

in the industry to have specific metes and bounds. Applicant finally argues that where a government agency requires a certain terminology, and defines such terminology, then it is this prescribed terminology that is binding (and actually required) and not an arbitrary dictionary definition. These arguments are not persuasive.

The Examiner respectfully submits that the FDA and the USPTO are different government agencies, and that metes and bounds of terminology required by one of those agencies is not necessarily applicable to the other. The Examiner points to the first sentence of the third paragraph of the FDA approval letter filed by Applicant on March 28, 2005 as Exhibit 3 in support of his position.

The definition of the term "implant" provided by the FDA and cited by Applicant in the remarks is directed to a noun. However, the term "non-implanted" as used by Applicant in the claims is an adjective that is used to modify a noun. Since Applicant's usage of the term is not consistent with the usage of the FDA, one cannot be certain that the definition of "non-implanted" as used by Applicant corresponds to and is consistent with the definition of the term "implant" provided by the FDA.

The Examiner maintains the position that absent any special definition of the term set forth in the specification of the instant application, one cannot be certain of the scope of this negative limitation. The Examiner respectfully submits that the specification of the instant application does not point one to the FDA for a definition of the term "non-implanted." As such, the Examiner contends that even a device that is an "implant" as defined by the FDA may be considered "non-implanted" as required by the claim limitations of the instant application, before said device is surgically inserted into the

body of a patient. Therefore, one cannot be certain of the metes and bounds of this term and thus the scope of the aforementioned claims.

In view of the foregoing, the rejection of claims 1-13 and 16 under 35 U.S.C. 112, second paragraph, as being indefinite has been maintained.

11. Applicant's arguments filed March 28, 2005 with regard to the claim rejections under 35 USC § 102(e) have been fully considered but they are not persuasive. Applicant contends that the Guice reference is limited to use in animals and does not "anticipate" the claims of the instant application because the device of Guice is not adapted to be self-applied by a human subject into the human vagina. This argument is not persuasive.

With regard to Applicant's arguments that defining the system using functional terms as being "adapted to be self-applied *by a human*" is entirely proper as clearly set forth in MPEP Section 2173.05(g), the Examiner respectfully submits that no previous Office Action has indicated that Applicant's use of this particular functional language is improper. The section of the MPEP pointed to by Applicant is directed more toward issues regarding 35 USC § 112, first and second paragraphs, than it is to rejections under 35 USC § 102. No rejections under 35 USC § 112, first and second paragraphs, have been set forth by the Office with respect to this limitation. Regarding Applicant's assertion that the beginning of the second paragraph of MPEP Section 2173.05(g) states that "a functional limitation must be evaluated and considered, just like any other limitation of the claim," the Examiner respectfully submits that this functional limitation has been evaluated and considered. The second sentence of said paragraph pointed to by Applicant states that "a functional limitation is often used in association with an

element... to define a particular *capability* or purpose that is served by the recited element." As discussed in detail in the Office Action of December 16, 2004, the Examiner contends that there is nothing in the structure of the Guice probes that would prevent the probes from being inserted into the human vagina. That is, a human would be *capable* of self-inserting one of the Guice probes illustrated in Figures 17-19 into the vagina of said human whether or not the FDA approves or irregardless of whether it would be advisable to do so. Once disposed with a human vagina, a Guice probe would be *capable* of functioning properly to sense vaginal conditions, such as the temperature of vaginal walls or a general temperature within the interior of the vaginal cavity. Since the Guice probes meet all of the structural limitations of the claims and are capable of performing the intended use of the claims.

In response to applicant's argument that Guice fails to suggest that the probe is adapted to be self-applied *by a human into the human vagina*, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Although Applicant points to MPEP Section 2115 in an attempt to obviate this argument, the Examiner respectfully submits MPEP Section 2114 provides support for this argument.

Although Applicant repeatedly contends that the FDA clearly distinguishes between humans and animals, the Examiner respectfully submits that the FDA and the USPTO are different government agencies, and that requirements and definitions accepted by one of those agencies are not necessarily applicable to the other. The

Examiner points to the first sentence of the third paragraph of the FDA approval letter filed by Applicant on March 28, 2005 as Exhibit 3 in support of his position.

The Examiner points out that the "non-implanted" limitation of the instant application can be loosely interpreted to include probes that the FDA defines as "implants" before those probes are surgically inserted into the body. Since the human body is nonstatutory subject matter and may not be positively recited in the claims, the "implants" of Guice may meet the "non-implanted" limitation of the claims prior to being inserted into the body of the subject. Irregardless of whether the "implants" of Guice have been inserted into the body of the subject, the combination probe, transceiver and power source of Guice still includes means for sensing vaginal conditions; and therefore, discloses all of structural limitations of the aforementioned claims.

In view of the foregoing, the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102(e) as being anticipated by Guice et al. ('390) has been maintained.

With regard to claim 16, Applicant contends that the combination probe, transceiver and power source of the Guice device is not non-expandable and not non-compressible. While the Examiner does not concede that this argument is persuasive because the claim does not define along what cross-section the unit is non-expandable and non-compressible, this argument is moot in view of the new ground of rejection citing Blythe that is set forth hereinabove.

12. The declarations under 37 CFR 1.132 tiled November 30, 2004 are insufficient to overcome the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102 (e) based upon Guice et al. as set forth in the last Office action because:

The declarations refer only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness/non-anticipation is commensurate in scope with the claims. See MPEP Section 716.

Moreover, the declarations provide the opinions of two "experts" in the field of Obstetrics and Gynecology, yet both declarations fail to set forth facts that sufficiently prove that the Guice implant units are not *capable* of use in a human. Both declarations attempt to point to several teachings from the Guice reference as evidence that the Guice implant units are not acceptable for human use and are not "non-implanted" devices. However, the teachings of Guice (e.g., the use of adhesives and tools to install the implant units) pointed to by Dr. Jayne and Dr. Wharton are not necessarily requirements of all embodiments of the Guice system as evident from the disclosure of paragraph [0042] of the Guice reference. The declaration of Dr. Jayne further repeatedly alleges that the CCFDA standards and regulations and safety concerns support that the implant units of Guice may not be used in a human vagina; however, the declaration still fails to provide factual evidence to support his position, such as the particular definitions of those (CFDA standards and regulations and safety concerns" that Dr. Jayne refers to. The lack of factual evidence provided in the declarations of Dr. Jayne and Dr. Wharton render the declarations insufficient to overcome the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102(e) as anticipated by Guice et al.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of non-anticipation and nonobviousness fails to outweigh the evidence of anticipation.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sundhar ('238) teaches a non-implanted electronic ovulation monitor.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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July 8, 2005